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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,993	12/28/2001	Susan McConnell	G&C 130.39-US-01	1833

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,993

Applicant(s)

MCCONNELL ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, 9-25, 27, 30-37, 39, 43-59, 62, 64-68 and 103-106 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 9-25, 27, 30-37, 39, 43-59, 62, 64-68, 103-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Examiner acknowledges the addition of new claims 103-106, cancelled claims 3, 6-8, 26, 28-29, 40-42, 60-61, 63 and 69-102, and amended claims 1, 22, 24, 35, 36, 56, 58 and 59. Currently claims 1, 2, 4, 5, 9-25, 27, 30-37, 39, 43-59, 62, 64-68 and 103-106 are pending for examination in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 13, 14, 17, 18, 19, 20, 22, 23, 24, 25, 27, 30-37, 39, 47, 48, 51-54, 56-59, 62, and 65-68 are rejected under 35 U.S.C 102(b) as being anticipated by Dugmore (WO 00/56384). Dugmore discloses an adjustable needle assembly device.

Regarding claims 1, 2, 4, 5, 13, 14, 17, 18, 19, 20, 22, 23, 24, 25, 27, 30-37, 39, 47, 48, 51-54, 56-59, 62, and 65-68, Dugmore discloses a flexible conduit housing (Figures 2A-C) and a base with a spool cartridge (Figures 9-11) that holds the flexible conduit and has a cover attached to the base (26) with an end (56) that is adapted to engage an infusion device (64).

Additionally, Dugmore discloses a device that is capable of infusing insulin into the body through the flexible conduit (12) via reservoir (74) (Figure 2A) to treat diabetes, wherein the flexible element can be dispensed to a certain length (Figures 2A-2C).

Art Unit: 3763

Dugmore discloses a spool (Figures 3A-3C) that can dispense the conduit to fixed length via the directional knob (80). The knob is driven under a ratchet and friction system (Figure 10, 11) that allows for retention at a fixed length.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-11, 15, 43-45, and 49 are rejected under 35 U.S.C 103(a) as being unpatentable over Dugmore in view of Peterson (US2003/0098067). Dugmore meets the claim limitations as described above except the center spool cartridge being replaceable.

However, Peterson teaches a gas-tubing reel.

Regarding claims 9-11, 15, 43-45 and 49, Peterson teaches a tubing reel that teaches a replaceable/removable spool (Figures 2-3, [0001]).

At the time of the invention, it would have been obvious use the replaceable/removable spool of Peterson with the system of Dugmore because it allows the housing to be reusable and allows for the ability to sterilize the different parts more effectively. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Peterson.

Additionally, It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the spool of Dugmore replaceable to make the housing reusable and allows for the ability to sterilize the different parts more effectively, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Newin v. Erlichman*, 168 USPQ 177 (BdPatApp&Int 1969).

Claim Rejections - 35 USC § 103

Claims 12, 16, 21, 46, 50, 55 and 64 are rejected under 35 U.S.C 103(a) as being unpatentable over Dugmore in view of Novosel (5,975,120). Dugmore meets the claim limitations as described above except the tubing being dispensed from each end of the conduit housing with a clamshell shape.

However, Novosel teaches and automatically retractable gas tubing feed spool.

Regarding claims 12, 16, 46, 50 and 64, Novosel teaches a tubing reel that comprises a reel with a tubing hub that allows for the tubing to be withdrawn from both ends to extend and retract the tubing into the clamshell shaped housing (Figures 1-2).

At the time of the invention, it would have been obvious to add the tubing hub of Novosel to the system of Dugmore to incorporate the extension of the medical conduit from both ends to allow for connection to devices that span different distances. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Novosel.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 103-106 are rejected under 35 U.S.C. 102(e) as being anticipated by Buchan (6,327,507).

Regarding claims 103-106, Buchan discloses a multiple-extendable leadwire device comprising a flexible conduit housing with a base (102), cover (136), flexible conduit (110) that is adapted to be connected to a sensor and various other medical devices (EKG, EEG) used to monitor a physiological condition, and in interface for mounting the housing (Figure 1, col 2, ln 45-69).

Response to Arguments

Applicant's arguments filed 8/22/2006 have been fully considered but they are not persuasive. In response to applicant's argument regarding the Dugmore reference (see above rejection), Applicant's representative asserts that the end of Dugmore is not adapted to connect to an infusion device, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Additionally, in response to applicant's argument that the references fail to show certain features of applicant's invention (end connected to infusion **pump**), it is noted that the features upon which applicant relies (i.e., infusion **pump**) are not recited in the rejected claim(s). Applicant has claimed an infusion device of which the device in Dugmore is capable of infusing a substance. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. **See *In re Van Geuns***, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 9/8/2006

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